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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,420	10/11/2005	Reiko Kawamura	P26669	6272

7055 7590 01/24/2007

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/24/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,420	KAWAMURA ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 08/2006 & 08/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "wherein the vegetable oil is a vegetable oil having an iodine value higher than 100 or a mixture thereof" is confusing. It is not clear what the "mixture thereof" recited in the claim refers to, as there is only one vegetable oil recited in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto et al. (New England Journal of Medicine), Muto et al. (US 5,852,057), Rinaldi et al. (5,891,470) and Hitoshi et al. (JP 63-166824).

A soft capsule preparation which comprises a dispersion of (2E, 4E, 6E, 10E)-3,7,11,15- tetramethyl-2,4,6,10,14-hexadecapentaenoic acid in a vegetable oil filled in a soft capsule comprising a shell having a light blocking effect is claimed. Dependent claims are drawn to the capsule preparation wherein the capsule additionally comprises particular surfactants, vegetable oils and light blocking agents, and wherein the capsule is made of succinyl gelatin.

Muto et al. (New England Journal of Medicine) beneficially teach a capsule preparation which comprises polyprenoic acid (3,7,11,15- tetramethyl-2,4,6,10,14-hexadecapentaenoic acid) (see e.g. page 1562 Study Design and, figure 1). Muto et al. also teach that the capsules are soft, made of gelatin, and that they are opaque (i.e. in a capsule comprising a shell having a light blocking effect). The light blocking effect of the shell would intrinsically be due to a light blocking agent. Muto et al. do not explicitly teach that the capsule preparation comprises the particular vegetable oils, surfactants, and light blocking agents instantly claimed

Muto et al. (US 5,852,057) beneficially teach 3,7,11,15- tetramethyl-2,4,6,10,14-hexadecapentaenoic acid , which is an acyclic retinoid (see e.g. col 2, lines 29-35). Muto et al. further beneficially teach that the compound (in capsules) was administered to patients participating in a study, and that the placebo group of patients were administered a capsule containing peanut oil alone (see e.g. col 3, lines 1-10). Muto et al. do not explicitly teach that the active capsule preparation (with 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid) contained peanut or another vegetable oil, though one would assume that because the placebo contained peanut oil

alone, the active capsule would also comprise peanut oil in addition to the active ingredient (3,7,11,15- tetramethyl-2,4,6,10,14-hexadecapentaenoic acid).

Rinaldi et al. beneficially teach that retinoids are sensitive to light and should be stored in opaque or colored containers (see e.g. col 1, lines 9-18).

Hitoshi et al. beneficially teach a semi transparent (which reads on opaque) soft gelatin capsule comprising titanium dioxide which is useful for encapsulating light unstable drugs (see e.g. English abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a soft, opaque gelatin capsule comprising 3,7,11,15- tetramethyl-2,4,6,10,14-hexadecapentaenoic acid and a vegetable oil based upon the beneficial teachings of Muto et al. (New England Journal of Medicine and US 5,852,057) that such a capsule is useful in treating hepatocellular carcinoma. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in preparing the capsule disclosed by Muto et al. and additionally using a light blocking agent such as titanium dioxide as beneficially taught by Hitoshi et al. based upon the beneficial teaching of Rinaldi et al. that retinoids (which includes 3,7,11,15- tetramethyl-2,4,6,10,14-hexadecapentaenoic acid) are light sensitive. The adjustment of particular conventional working conditions (e.g. selecting particular surfactants, vegetable oils or coloring agents) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTOPHER R. TATE
PRIMARY EXAMINER